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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MCDERMOTT WILL & EMERY LLP 600 13TH STREET, N.W. WASHINGTON, DC 20005-3096			EXAMINER BUI, KIM T	
			ART UNIT 3626	PAPER NUMBER

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/845,066	KEHR ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Kim T. Bui	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 07 May 2001.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-34,36 and 37 is/are pending in the application.  
 4a) Of the above claim(s) 20-34,35,36 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-19 and 37 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) 1-34 and 37 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-19 and 37, drawn to method for modifying medical protocol, classified in class 705/2.
  - II. Claims 20, drawn to a method for providing services to customer, classified in 705/1.
  - III. Claims 21 and 27-34, drawn to a method for providing medical treatment for a patient, classified in 705/2.
  - IV. Claim 22, drawn to a method for assigning and downloading software, classified in 717/137.
  - V. Claim 23, drawn to a method for strong medication in containers of different sizes and functional features, classified in class 206/216.
  - VI. Claims 24-25, drawn to a method for providing and communicating the medication consumption information to the suppliers along the pharmaceutical supply chain, classified in 705/28.
  - VII. Claim 26, drawn to a method for providing analysis of the effectiveness of a pharmaceutical compound by record keeping and correlating, classified in 705/3.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III, IV, V, VI, VII are related as subcombinations disclosed as usable in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention I has separate utility as

updating medical data, invention II has separate utility such as customer service, invention III has separate utility such as method for proving medical treatment to a patient, invention IV has separate utility such as software application management (i.e., assigning, downloading), invention V has separate utility such as providing medication receptacle device with functional features, invention VI has separately utility such as inventory control for medication supply chain, inventory VII has separate utility such as record keeping and processing for analyzing the effectiveness of pharmaceutical compound.

Because these inventions are distinct for the reasons given above and have acquires separate status in the art by different classification, the search required for one group is not required for the others, and/or because of their recognized divergent subject matter. Restriction for examination as indicated is proper.

During the telephonic conversation with Mr. Stephen Baker on 8/22/05, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-19 and 37. Affirmation of this election must be made by applicant in replying to this Office Action, Claims 20-34 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non- elected invention.

Claim 35 was cancelled in the preliminary amendment filed 02/07/2002. Claim 36 depends on a cancelled claim, is therefor withdrawn from consideration by the examiner.

***Specification***

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The abstract of the disclosure is objected to because the abstract should be limited to 150 words. Correction is required. See MPEP § 608.01(b).

#### ***Claim Rejections - 35 USC § 101***

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1, 3-19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The basis of this rejection is set forth in a two-prong test of:

- (1) whether the invention is within the technological arts; and
- (2) whether the invention produces a useful, concrete, and tangible result.

For a claimed invention to be statutory, the claimed invention must be within the technological arts. Mere ideas in the abstract (i.e., abstract idea, law of nature, natural phenomena) that do not apply, involve, use, or advance the technological arts fail to promote the "progress of science and the useful arts" (i.e., the physical sciences as opposed to social sciences, for example) and therefore are found to be non-statutory

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subject matter. For a process claim to pass muster, the recited process must somehow apply, involve, use, or advance the technological arts in a nontrivial manner.

(A) In the present case, claims 1 and 13 do not apply, involve, use, or advance the technological arts. The claims only constitute an idea of how to modify the medical protocols comprising the steps for determining patient characteristics/entering data elements; comparing data, updating and transmitting data, converting, transmitting/communicating files/queries, therefore, do not represent a practical application of the idea to advance the technology art. These steps do not apply, involve, use, or advance the technological arts since they can be performed in the mind of the user or by use of a pencil and paper. These steps only constitute an idea of how to modify data.

(B) Dependent claims 3-12 and 14-19 do not further recites steps that apply, involve, use, or advance the technological arts steps in a non-trivial manner.

The recitation of the step for transmitting data in the independent claims 1, 13 and the database, dial up, Internet access recited in the dependent claims 11, 19, 15, 16 do not add processing steps and means to advance the technological art in a non trivial manner.

In addition, for a claimed invention to be statutory, it must produce a useful, concrete, and tangible result. In the present case, the claimed invention produces a method for transmitting, comparing, communicating patient information (i.e., repeatable) used in modifying medical protocol (i.e., useful and tangible).

Although the recited process produces a useful, concrete, and tangible result, since the claimed invention, as a whole, is not within the technological arts as explained above, claims 1, 3-19 are deemed to be directed to non-statutory subject matter.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 3, 5-8, 10, 13-19, 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- (A) As per claim 3, "said responses" on line 2 lacks antecedent basis;
- (B) As per claim 8, "said messages" on line 1 lacks antecedent basis;
- (C) As per claim 10, "said source patient" on line 3 lacks proper antecedent basis;
- (D) As per claim 13, the preamble of the claim recites a method for modifying medical protocol. However, there is/are no step(s) in the body of the claim to perform the recited "modifying" function.
- (E) As per claim 14, "said database" on line 1 lacks antecedent basis;
- (F) As per claim 37, "the group of selected patient protocols" on line 7 lacks clear antecedent basis;
- (G) Independent claims 5-8, 14-19 incorporate the deficiencies of the claims they depend on and are therefore rejected.

***Claim Rejections - 35 USC § 102***

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8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 1, 3, 4, 6-10, 12, 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Linder et al (6681003).

(A) As per claim 1, Linder et al disclose a method for modifying medical protocols comprising:

a. determining characteristics (i.e. password, demographic and medical information) of target patient(s) having protocol information capable of being updated. Linder et al, col. 8, lines 40-47, lines 53-59.

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b. comparing patient characteristics with stored characteristics (all patient's identification, password, medical record, baseline) to find a match. Linder et al., col. 7, lines 53-54, col. 8, lines 46-48 and lines 53-59.

c. updating (i.e., adjusting) protocol information (i.e., medical profile, operating parameter, treatment etc... ) of the patient(s) to the patient monitoring device, the protocol information being copied from the stored profiles of the patients. Linder et al., the abstract, col. 5, lines 42-50, lines 53-60, and col. 9, lines 35-49.

d. transmitting the updated protocol information to the patient monitoring device. Linder et al., the abstract, col. 9, lines 22-27.

(B) As per claim 3, Linder et al teaches the step for communicating the responses to the information system on col. 8, lines 2-5.

(C) As per claim 4, Linder et al. teaches the communicating of series of messages on col. 4, lines 47-66, col. 6, lines 50-53.

(D) As per claim 6, Linder et al teaches the step for requiring the targeted patients to follow a series of instructions on col. 6, lines 53-55.

(E) As per claim 7, Linder et al teaches the step for accessing health status data. Linder et al., col. 6, lines 29-31, col. 7, lines 1-2.

(F) As per claim 8, Linder et al teaches that the message(s) is served to insure a correct operation of the device and/or patient compliance, such compliance or proper operation of the device is a direct function of patient measurements and therefore is of value in monitoring the patients. Linder et al. col. 4, lines 44-59.

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(G) As per claim 9, Linder et al. teaches the stored (i.e., source) patient characteristics includes patient demographic (i.e. age, gender etc.. ) and medical profiles with physiological measurements, clinical setting, medication on col. 8, lines 49-56, col. 5, lines 45-47, col. 4, lines 7-10, col. 7, lines 44-46 and lines 53-54.

(H) As per claim 10, Linder et al teaches the step relating source characteristics to a combination of source characteristics by analyzing multiple sets of patient characteristics to develop trends on col. 5, lines 6-8.

(I) As per claim 12, Linder et al teaches the central database server for storing information and the use of Internet to distribution of data to remote computers, and to other preexisting database such as "database type gathering of information for maintenance personnel to observe trends and provide preventive services ". See Linder et al. col. 5, lines 26-40 and col. 4, lines 1- 4.

(J) As per claim 37, Linder et al teaches a method for modifying medical protocol stored in database system comprising:

- a. providing a database server containing medical protocols for a plurality of patients . Linder et al., the abstract, Fig. 1, col. 3, lines 55-61, col. 8, lines 45-61.
- b. providing a patient device capable of communicating with database server. Linder et al., the abstract, Fig. 1, col. 3, lines 55-58, col. 7., lines 25-31.
- c. communicating using the device to select the group of patients based on specific patient characteristics ( i.e., search done for all patient's who last name begin with the letter R). Linder et al., col. 8, lines 43-45.

d. using patient device to modify the patient protocols by electronic communication means in the same way. Linder et al., col. 9, lines 33-48, col. 7, lines 1-10 and col. 5, lines 53-60.

10. Claims 13-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Surwit et al (6589169).

(A) As per claim 13, Surwit et al. teaches a method for modifying medical protocol in a health information system comprising the steps of:

a. entering elements of medical protocol specific to patient(s) to be transmitted to a server database containing files pertaining to the patients. Surwit et al., col. 2, lines 58-60, col. 6, line 60 to col. 7, line 2, col. 7, lines 60-67 and col. 8, lines 25-30.

b. transmitting a file containing updating and instruction (i.e. changes made to medical doses) to monitoring device. Surwit et al., col. 12, lines 55-62, col. 14, lines 9-14.

c. converting the file (i.e., text to voice) into a series of queries presented to the patients. Surwit et al., col. 19, lines 5-28, Fig. 10A, col. 19, lines 49-51 and col. 8, lines 49-54.

d. communicating the responses back to a device for report generating. Surwit et al., col. 17, lines 29-33, col. 18, lines 43-49.

(B) As per claim 14, Surwit et al. teaches that the responses are communicated to the server database on col. 8, lines 15-17, lines 25-35 and lines 45-53.

(C) As per claim 15, Surwit et al. discloses the PPM device for entering medical protocol as a personal computer, and suggests that the device can be modified to be

used in various communication technologies (i.e., wireless communication, satellite communication). Surwit et al., col. 9, lines 25-40.

(D) As per claim 16, Surwit et al. teaches the dial-in and Internet communication on col. 9, lines 40-52.

(E) As per claim 17, Surwit et al. teaches medication dosage, type, dietary, reminder on col. 4, lines 18-19, col. 8, lines 47-49 and col. 21, lines 26-28

(F) As per claim 18, Surwit et al. teaches the steps for relating the elements in the medical protocol to algorithm driven events that are based on entered data on col. 8, lines 44-53.

#### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 2, 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Linder et al. (6681003) in view of Iliff (2003/0153819 A1).

(A) As per claim 2, Linder et al teaches that the message(s) to instruct the patients for a correct operation of the device and/or patient compliance, such compliance or proper operation of the device is a direct function of the patient measurements and therefore is of value in monitoring the patients. Linder et al., col. 4, lines 44-59. Linder et al. fails to expressly recite the step for converting the protocol information into series of queries and responses for report generation. This, however, is well known in the art as

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evidenced by IIiff. IIiff teaches an interactive healthcare system for monitoring patients including a Script Engine for converting the codes in the medical files (i.e. protocol information) into a series of queries presented to patients for responses and report generation. IIiff, page 3, paragraph 0081, page 8, paragraphs 0137, 0139, page 16, paragraph 0231, page 18, paragraphs 0251, 0258.

It would have been obvious to one having ordinary skill in the art at the time of the invention to include queries/ responses for report generation with the motivation of providing medical services accessible at off hours, from home when needed, thereby saving time and costs for trivial contacts. IIiff, page 24, paragraphs 0372, 0391.

(B) As per claim 5, Linder et al suggests machine implemented therapeutic action and treatment if applicable on col. 7, lines 3-4, col. 9, line 2. In addition, it is well known in the art to include the step for instructing the patients for taking medication into the healthcare system as evidenced by IIiff. IIiff teaches a patient monitoring system including modules for treatment and medication. See IIiff, elements 248, 250 in Fig. 3, and page 17, paragraph 0249.

It would have been obvious to one having ordinary skill in the art at the time of the invention to include a taking medication event with the motivation of optimizing the system's operation by adding standard advise and treatment. IIiff, page 24, paragraph 0398..

13. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Linder et al. (6691003) in view of Xue et al. (6463320).

(A) As per claim 11, Linder et al. fails to recite ODBC database. However, the use of ODBC database is well known in the prior art of healthcare data-processing system as evidenced by Xue et al. Xue et al., col. 1, lines 60-65. It would have been obvious to one having ordinary skill in the art to employ ODBC database into Linder's system with the motivation of conforming to standard practice for compatibility. Xue et al. col. 2, lines 27-38.

14. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Surwit et al. (6589169) in view of Xue et al. (6463320).

(A) As per claim 19, Surwit et al. fails to recite ODBC database. However, the use of ODBC database is well known in the prior art of healthcare data-processing system as evidenced by Xue et al. Xue et al., col. 1, lines 60-65. It would have been obvious to one having ordinary skill in the art to incorporate ODBC database into Surwit's system with the motivation of conforming to standard practice for compatibility. Xue et al. col. 2, lines 27-38.

### ***Conclusion***

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. "Medical measurement apparatus" (5730124); " System for recording medication delivery to a patient" (US 2005/0119788); " Data collection System" (US 2002/0116509); "Method for controlling an Infusion Pump" (2002/0038392); "Patient interface system" (6409662); "Fault –tolerant remote reprogramming for patient worn medical device" (2003/0095648); " Apparatus for alerting patients and personnel for emergency situations" (5416695); " Disease

management system" (2001/0047125), " Alaris Medical Updates Third Quarter Outlook; Maintains Third Quarter and Full Year EPS Guidance", Business Editors & Health/Medical Writers. Business Wire. New York, Sep 12,2002, page 1, Document ID 173130431, Text Word count 953.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim T. Bui whose telephone number is 571-272-6768. The examiner can normally be reached on Monday-Friday from 8:30A.M. to 5:00P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KTB  
9/01/05.



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